

What we claim is:

- 1) A method for the treatment of bacterial infections, comprising:
administering parenterally an effective amount of a therapeutic agent, said therapeutic agent comprising:
at least one lytic enzyme produced by a bacteria infected with a bacteriophage specific for said bacteria, wherein said at least one lytic enzyme is selected from the group consisting of shuffled lytic enzymes, chimeric lytic enzymes, holin lytic enzymes, and combinations thereof and;
a carrier for delivering said at least one lytic enzyme to the site of the infection.
- 2) The method according to claim 1, wherein said at least one lytic enzyme is for the treatment of *Pseudomonas*.
- 3) The method according to claim 1, wherein said at least one lytic enzyme is for the treatment of *Streptococcus*.
- 4) The method according to claim 1, wherein said at least one lytic enzyme is for the treatment of *Staphylococcus*.
- 5) The method according to claim 1, wherein said at least one lytic enzyme is for the treatment of *Clostridium*.
- 6) The method according to claim 1, wherein said further therapeutic agent comprises a buffer

that maintains pH of the composition at a range between about 4.0 and about 9.0.

7) The method according to claim 6, wherein the buffer maintains the pH of the therapeutic agent at the range between about 5.5 and about 7.5.

8) The method according to claim 6, wherein said buffer comprises a reducing reagent.

9) The method according to claim 8, wherein said reducing reagent is dithiothreitol.

10) The method according to claim 6, wherein said buffer comprises a metal chelating reagent.

11) The method according to claim 10, wherein said metal chelating reagent is ethylenediaminetetracetic disodium salt.

12) The method according to claim 6, wherein said buffer is a citrate-phosphate buffer.

13) The method according to claim 1, further comprising a bactericidal or bacteriostatic agent as a preservative.

14) The method according to claim 1, wherein said at least one lytic enzyme is lyophilized.

15) The method according claim 1, further comprising administering a concentration of about

100 to about 500,000 active enzyme units per milliliter of fluid in the wet environment of the nasal or oral passages.

16) The method according to claim 15, further comprising administering the concentration of about 100 to about 10,000 active enzyme units per milliliter of fluid in the wet environment of the nasal or oral passages.

17) The method according to claim 1, wherein said therapeutic agent is administered intravenously.

18) The method according to claim 1, wherein said therapeutic agent is administered intramuscularly.

19) The method according to claim 1, wherein said therapeutic agent is administered subcutaneously.

20) The method according to claim 1, wherein the therapeutic agent further comprises at least one complementary agent which potentiates the bactericidal activity of the at least one enzyme, said complementary agent being selected from the group consisting of penicillin, synthetic penicillins bacitracin, methicillin, cephalosporin, polymyxin, cefaclor, Cefadroxil, cefamandole nafate, cefazolin, cefixime, cefmetazole, cefoniod, cefoperazone, ceforanide, cefotanme, cefotaxime, cefotetan, cefoxitin, cefpodoxime proxetil, ceftazidime, ceftizoxime,

ceftriaxone, ceftriaxone moxalactam, cefuroxime, cephalexin, cephalosporin C, cephalosporin C sodium salt, cephalothin, cephalothin sodium salt, cephapirin, cephradine, cefuroximeaxetil, dihydratecephalothin, moxalactam, loracarbef, mafate and chelating agents in an amount effective to synergistically enhance the therapeutic effect of the at least one lytic enzyme.

5
21) The method according to claim 1, wherein said carrier comprises of distilled water, a saline solution, albumin, a serum, and any combinations thereof.

10
22) The method according to claim 1, wherein said carrier further comprises preservatives.

23) The method according to claim 22, wherein said preservatives comprise p-hydroxybenzoates.

15
24) The method according to claim 1, wherein said carrier comprises an isotonic solution for an injection, said isotonic solution comprising a compound selected from group consisting of sodium chloride, dextrose, mannitol, sorbitol, lactose, phosphate buffered saline, gelatin, albumin, a vasoconstriction agent and combinations

25) The method according to claim 24, wherein said further carrier further comprises DMSO.

20
26) The method according to claim 1, wherein said method is for the prophylactic treatment of infections.

27) The method according to claim 1, wherein said method is for the therapeutic treatment of infections.

28) The method according to claim 1, wherein said at least one said holin lytic enzyme is a shuffled holin lytic enzyme.

29) The method according to claim 1, wherein said at least one holin enzyme is a chimeric holin lytic enzyme.

30) The method according to claim 1, further comprising at least one lytic enzyme which is not selected from the group consisting of at least one shuffled lytic enzyme, chimeric lytic enzyme, and holin lytic enzyme.

31) A composition for the treatment of bacterial infections, comprising:

a therapeutic agent comprising:

an effective amount of at least one lytic enzyme produced by a bacteria infected with a bacteriophage specific for said bacteria, wherein said at least one lytic enzyme is selected from the group consisting of shuffled lytic enzymes, chimeric lytic enzymes, holin lytic enzymes, and combinations thereof, said at least one lytic enzyme having the ability to digest a cell wall of a specific said bacteria; and,

a carrier for the parenteral delivery of said at least one lytic enzyme to the site of the infection.

32) The composition according to claim 31, wherein the at least one lytic enzyme is for the treatment of *Pseudomonas*.

5 33) The composition according to claim 31, wherein the at least one lytic enzyme is for the treatment of *Streptococcus*

34) The composition according to claim 31, wherein the at least one lytic enzyme is for the treatment of *Staphylococcus*.

10 35) The composition according to claim 31, wherein the at least one lytic enzyme is for the treatment of *Clostridium*.

15 36) The composition according to claim 31, wherein said composition further comprises a buffer that maintains pH of the composition at a range between about 4.0 and about 9.0.

37) The composition according to claim 36, wherein the buffer maintains the pH of the composition at the range between about 5.5 and about 7.5.

20 38) The composition according to claim 36, wherein said buffer comprises a reducing reagent.

39) The composition according to claim 38, wherein said reducing reagent is dithiothreitol.

40) The composition according to claim 36, wherein said buffer comprises a metal chelating reagent.

41) The composition according to claim 40, wherein said metal chelating reagent is ethylenediaminetetracetic disodium salt.

42) The composition according to claim 36, wherein said buffer is a citrate-phosphate buffer.

43) The composition according to claim 31, further comprising a bactericidal or bacteriostatic agent as a preservative.

44) The composition according to claim 31, wherein said at least one lytic enzyme is lyophilized.

45) The composition according claim 31, further comprising administering a concentration of about 100 to about 500,000 active enzyme units per milliliter of fluid in the wet environment of the nasal or oral passages.

46) The composition according to claim 31, further comprising administering the concentration of about 1000 to about 100,000 active enzyme units per milliliter of fluid in the wet environment of the nasal or oral passages.

47) The composition according to claim 31, wherein said therapeutic agent is administered intravenously.

48) The composition according to claim 31, wherein said therapeutic agent is administered intramuscularly.

49) The method according to claim 31, wherein said therapeutic agent is administered subcutaneously.

50) The composition according to claim 31, wherein the therapeutic agent further comprises at least one complementary agent which potentiates the bactericidal activity of the lysine enzyme, said complementary agent being selected from the group consisting of penicillin, synthetic penicillins bacitracin, methicillin, cephalosporin, polymyxin, cefaclor, Cefadroxil, cefamandole nafate, cefazolin, cefixime, cefmetazole, cefoniod, cefoperazone, ceforanide, cefotanme, cefotaxime, cefotetan, cefoxitin, cefpodoxime proxetil, ceftazidime, ceftizoxime, ceftriaxone, ceftriaxone moxalactam, cefuroxime, cephalixin, cephalosporin C, cephalosporin C sodium salt, cephalothin, cephalothin sodium salt, cephapirin, cephradine, cefuroximeaxetil, dihydratecephalothin, moxalactam, loracarbef, nafate and chelating agents in an amount effective to synergistically enhance the therapeutic effect of the lysin enzyme.

51) The composition according to claim 31, wherein said carrier is selected from the group consisting of distilled water, a saline solution, albumin, a serum, and any combinations

thereof.

52) The composition according to claim 31, wherein said carrier further comprises preservatives.

5 53) The composition according to claim 52, wherein said preservatives comprise p-hydroxybenzoates.

10 54) The composition according to claim 31, wherein said carrier comprises an isotonic solution for an injection, said isotonic solution comprising a compound selected from group consisting of sodium chloride, dextrose, mannitol, sorbitol, lactose, phosphate buffered saline, gelatin, albumin, a vasoconstriction agent and combinations thereof.

55) The composition according to claim 31, wherein said carrier further comprises DMSO.

15 56) The method according to claim 31, wherein said method is for the therapeutic treatment of infections.

57) The method according to claim 31, wherein said at least one said holin lytic enzyme is a shuffled holin lytic enzyme.

20 58) The method according to claim 31, wherein said at least one holin enzyme is a chimeric holin lytic enzyme.

- 59) ~~The method according to claim 31, further comprising at least one lytic enzyme which is not selected from the group consisting of at least one shuffled lytic enzyme, chimeric lytic enzyme, and holin lytic enzyme.~~

5

add
A

09752731.010301